First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

HOUSE ENROLLED ACT No. 1382

AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 15. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to

maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "covered individual" means an individual entitled to coverage under a state employee plan.

(d) As used in this section, "nonparticipating provider" means a health care provider that has not entered into a contract with a state employee plan to serve as a participating provider.

(e) As used in this section, "participating provider" means a health care provider that has entered into a contract with a state employee plan to provide health care services to covered individuals with an expectation of directly or indirectly receiving payment from the state employee plan.

(f) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been

approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's state employee plan, including the sponsor of the clinical trial.

(g) As used in this section, "state employee plan" means one (1) of the following:

(1) A self-insurance program established under section 7(b) of this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

(h) A state employee plan must provide coverage for routine care costs that are incurred in the course of a clinical trial if the state employee plan would provide coverage for the same routine care costs not incurred in a clinical trial.

(i) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(j) This section does not do any of the following:

(1) Require a state employee plan to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit a state employee plan from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement under a state employee plan for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

(k) This section does not create a cause of action against a person for any harm to a covered individual resulting from a clinical trial.

SECTION 2. IC 12-15-5-9.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY

1, 2009]: **Sec. 9.2. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The drug or device that is under evaluation in a clinical trial.

(2) Items or services that are:

(A) provided solely for data collection and analysis and not in the direct clinical management of an individual enrolled in a clinical trial;

(B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or

(C) provided solely to determine eligibility of an individual for participation in a clinical trial.

(d) The Medicaid program must provide coverage for routine care costs that are incurred in the course of a clinical trial if the Medicaid program would provide coverage for the same routine care costs not incurred in a clinical trial.

(e) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(f) This section does not do any of the following:

(1) Require the Medicaid program to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit the Medicaid program from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]:

Chapter 25. Coverage for Care Related to Clinical Trials

Sec. 1. As used in this chapter, "care method" means the use of a particular drug or device in a particular manner.

Sec. 2. As used in this chapter, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

Sec. 3. As used in this chapter, "contracted provider" means a health care provider that has entered into an agreement under IC 27-8-11-3 with an insurer that issues a policy of accident and sickness insurance.

Sec. 4. As used in this chapter, "covered individual" means an individual entitled to coverage under a policy of accident and sickness insurance.

Sec. 5. As used in this chapter, "noncontracted provider" means a health care provider that has not entered into an agreement to serve as a contracted provider.

Sec. 6. As used in this chapter, "policy of accident and sickness insurance" has the meaning set forth in IC 27-8-5-1.

Sec. 7. As used in this chapter, "routine care cost" means the

cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.

Sec. 8. (a) A policy of accident and sickness insurance must provide coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.

(b) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by contracted providers and noncontracted providers.

(c) This section does not do any of the following:

(1) Require an insurer that issues a policy of accident and sickness insurance to provide coverage for clinical trial services rendered by a contracted provider.

(2) Prohibit an insurer that issues a policy of accident and sickness insurance from providing coverage for clinical trial

services rendered by a contracted provider.

(3) Require reimbursement under a policy of accident and sickness insurance for services that are rendered in a clinical trial by a noncontracted provider at the same rate of reimbursement that would apply to the same services rendered by a contracted provider.

Sec. 9. This chapter does not create a cause of action against a person for any harm to a covered individual resulting from a clinical trial.

SECTION 4. IC 27-13-7-20.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 20.2. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "nonparticipating provider" means a health care provider that has not entered into an agreement described in IC 27-13-1-24.

(d) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than an enrollee's individual contract or group contract, including the sponsor of the clinical trial.

(e) An individual contract or a group contract must provide coverage for routine care costs that are incurred in the course of a clinical trial if the individual contract or group contract would provide coverage for the same routine care costs not incurred in a clinical trial.

(f) The coverage that must be provided under this section is

subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual contract or group contract, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(g) This section does not do any of the following:

(1) Require a health maintenance organization to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit a health maintenance organization from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement under an individual contract or a group contract for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

(h) This section does not create a cause of action against a person for any harm to an enrollee resulting from a clinical trial.

SECTION 5. [EFFECTIVE JULY 1, 2009] **(a) IC 5-10-8-15, as added by this act, applies to a state employee health plan that is established, entered into, issued, delivered, amended, or renewed after June 30, 2009.**

(b) IC 12-15-5-9.2, as added by this act, applies to a Medicaid risk based managed care contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(c) IC 27-8-25, as added by this act, applies to a policy of accident and sickness insurance that is issued, delivered, amended, or renewed after June 30, 2009.

(d) IC 27-13-7-20.2, as added by this act, applies to an individual contract or a group contract that is entered into, delivered, amended, or renewed after June 30, 2009.

(e) This SECTION expires July 1, 2014.

Speaker of the House of Representatives

President of the Senate

President Pro Tempore

Governor of the State of Indiana

Date: _____ Time: _____